(3) The Leader, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(4) The Medicated Feeds Specialist, Medicated Feeds Team, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(e) These officials may not further redelegate these authorities.

§ 5.502 Issuance of notices, proposals, and orders relating to new animal drugs and medicated feed mill license applications.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and proposals to refuse approval or to revoke approval of medicated feed mill license applications, and supplements thereto, submitted under section 512(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104–250);

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and medicated feed mill licenses, corresponding to said act on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

(c) These officials may not further redelegate these authorities.

§ 5.503 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(D)(iv) and (c)(2)(F) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act (21 U.S.C. 360b(b)(2)), and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act (21 U.S.C. 360b(b)(1)):

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) These officials may not further redelegate this authority.

§ 5.504 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new animal drugs and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs (Commissioner) under section 512(e), (m)(4)(B)(ii), and (m)(4)(B)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(e), (m)(4)(B)(ii), and (m)(4)(B)(iii)) regarding the issuance of written notices:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

(b) These officials may not further redelegate this authority.

§ 5.505 Termination of exemptions for new drugs for investigational use in animals.

(a) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) These officials may not further redelegate this authority.

Subpart H—Radiation Control; Redelegations of Authority

§ 5.600 Variances from performance standards for electronic products.

(a) The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.601 Exemption of electronic products from performance standards and prohibited acts.

(a) The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 534(a)(5) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360kk(a)(5)) and to exempt an electronic product or class of products from all or part of the provisions of section 538(a) of the act (21 U.S.C. 360oo(a)) under section 538(b) of the act (21 U.S.C. 360oo(b)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(b) These officials may not further redelegate this authority.

§ 5.602 Testing programs and methods of certification and identification for electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to review and evaluate industry testing programs under section 534(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360kk(g)) and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 534(h) of the act (21 U.S.C. 360kk(h)).

(b) These officials may not further redelegate this authority.

§ 5.603 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs (Commissioner), relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 534 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360kk) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance, CDRH, and the Division Directors, Office of Compliance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 535(e) of the act (21 U.S.C. 360ll(e)) and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to: